WHAT IS CLAIMED IS

1. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer mixture in an amount effective to protect said biological material from said radiation; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

2. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the residual solvent content of said biological material;

(ii) adding to said biological material at least one stabilizer mixture; and

(iii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the level of said residual solvent content and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i) and (ii) may be performed in inverse order.

3. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the temperature of said biological material;

(ii) adding to said biological material at least one stabilizer mixture; and

(iii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the temperature and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i) and (ii) may be performed in inverse order.

4. The method according to claim 2, wherein said solvent is water.

5. The method according to claim 4, wherein said residual water content is reduced by the addition of an organic solvent.

6. The method according to claim 2, wherein said solvent is an organic solvent.

7. The method according to claim 2, wherein said biological material is suspended in an organic solvent following reduction of said residual solvent content.

8. The method according to claim 1, 2, 3 or 86, wherein said effective rate is not more than about 3.0 kGy/hour.

9. The method according to claim 1, 2, 3 or 86, wherein said effective rate is not more than about 2.0 kGy/hr.

10. The method according to claim 1, 2, 3 or 86, wherein said effective rate is not more than about 1.0 kGy/hr.

11. The method according to claim 1, 2, 3 or 86, wherein said effective rate is not more than about 0.3 kGy/hr.

12. The method according to claim 1, 2, 3 or 86, wherein said effective rate is more than about 3.0 kGy/hour.

13. The method according to claim 1, 2, 3 or 86, wherein said effective rate is at least about 6.0 kGy/hour.

14. The method according to claim 1, 2, 3 or 86, wherein said effective rate is at least about 18.0 kGy/hour.

15. The method according to claim 1, 2, 3 or 86, wherein said effective rate is at least about 30.0 kGy/hour.

16. The method according to claim 1, 2, 3 or 86, wherein said effective rate is at least about 45 kGy/hour.

17. The method according to claim 1, 2, 3 or 86, wherein said biological material is maintained in a low oxygen atmosphere.

18. The method according to claim 1, 2, 3 or 86, wherein said biological material is maintained in an atmosphere comprising at least one noble gas.

19. The method according to claim 18, wherein said noble gas is argon.

20. The method according to claim 1, 2, 3 or 86, wherein said biological material is maintained in a vacuum.

21. The method according to claim 2, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying, and vitrification.

22. The method according to claim 2, wherein said residual solvent content is less than about 15%.

23. The method according to claim 2, wherein said residual solvent content is less than about 3%.

24. The method according to claim 2, wherein said residual solvent content is less than about 2%.

25. The method according to claim 2, wherein said residual solvent content is less than about 1%.

26. The method according to claim 2, wherein said residual solvent content is less than about 0.5%.

27. The method according to claim 2, wherein said residual solvent content is less than about 0.08%.

28. The method according to claim 1, 2, 3 or 86, wherein at least one sensitizer is added to said biological material prior to said step of irradiating said biological material.

29. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture comprises at least three stabilizers.

30. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one antioxidant.

31. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one free radical scavenger.

32. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one combination stabilizer.

33. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one ligand.

34. The method according to claim 33, wherein said ligand is heparin.

35. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one stabilizer that reduces damage due to reactive oxygen species.

36. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture contains at least one stabilizer selected from the group consisting of: ascorbic acid or a salt or ester thereof;

glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silimarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and mixtures of two or more thereof.

37. The method according to claim 36, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid and mixtures of uric acid, or a salt or ester thereof; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

38. The method according to claim 1, 2, 3 or 86, wherein said stabilizer mixture comprises ascorbic acid or a salt or ester thereof.

39. The method according to claim 1, 2, 3 or 86, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

40. The method according to claim 39, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

41. The method according to claim 1, 2, 3 or 86, wherein said radiation is gamma radiation.

42. The method according to claim 1, 2, 3 or 86, wherein said radiation is E-beam radiation.

43. The method according to claim 1, 2, 3 or 86, wherein said radiation is visible light.

44. The method according to claim 1, 2, 3 or 86, wherein said radiation is ultraviolet light.

45. The method according to claim 1, 2, 3 or 86, wherein said radiation is x-ray radiation.

46. The method according to claim 1, 2, 3 or 86, wherein said radiation is polychromatic visible light.

47. The method according to claim 1, 2, 3 or 86, wherein said radiation is infrared.

48. The method according to claim 1, 2, 3 or 86, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

49. The method according to claim 1, 2, 3 or 86, wherein said irradiation is conducted at ambient temperature.

50. The method according to claim 1, 2, 3 or 86, wherein said irradiation is conducted at a temperature below ambient temperature.

51. The method according to claim 1, 2, 3 or 86, wherein said irradiation is conducted below the freezing point of said biological material.

52. The method according to claim 1, 2, 3 or 86, wherein said irradiation is conducted below the eutectic point of said biological material.

53. The method according to claim 1, 2, 3 or 86, wherein said irradiation is conducted at a temperature above ambient temperature.

54 A composition comprising at least one biological material and at least one stabilizer mixture in an amount effective to preserve said biological material for its intended use following sterilization with radiation.

55. The composition according to claim 54, wherein said stabilizer mixture contains at least one stabilizer selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; diosmin; silymarin; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate, vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; hydroquinonesulfonic acid; a mixture of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; a mixture of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; a mixture of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and a mixture of uric acid, or a salt or ester thereof and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a

salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid.

56. The composition of claim 54, wherein the residual solvent content of said biological material is sufficiently low to preserve said biological material, during sterilization by irradiation, for its intended use following sterilization with radiation.

57. The composition of claim 56, wherein said residual solvent content is less than about 15%.

58. The composition of claim 56, wherein said residual solvent content is less than about 10%.

59. The composition of claim 56, wherein said residual solvent content is less than about 5%.

60. The composition of claim 56, wherein said residual solvent content is less than about 2%.

61. The composition of claim 56, wherein said residual solvent content is less than about 1%.

62. The composition of claim 56, wherein said residual solvent content is less than about 0.5%.

63. The composition of claim 56, wherein said residual solvent content is less than about 0.08%.

64. The composition of claim 56, wherein said biological material is glassy or vitrified.

65. The composition of claim 54, wherein said biological material is selected from the group consisting of monoclonal immunoglobulins, polyclonal immunoglobulins, glycosidases, sulfatases, urokinase and Factor VIII.

66. The composition of claim 56, wherein the concentration of said biological material is at least about 0.5%.

67. The composition of claim 56, wherein the concentration of said biological material is at least about 1%.

68. The composition of claim 56, wherein the concentration of said biological material is at least about 5%.

69. The composition of claim 56, wherein the concentration of said biological material is at least about 10%.

70. The composition of claim 56, wherein the concentration of said biological material is at least about 15%.

71. The composition of claim 56, wherein the concentration of said biological material is at least about 20%.

72. The composition of claim 56, wherein the concentration of said biological material is at least about 25%.

73. The composition of claim 56, wherein the concentration of said biological material is at least about 50%.

74. A method of treating a disease or deficiency in a mammal comprising administering to a mammal in need thereof an effective amount of a biological preparation which has been sterilized according to the method according to claim 1, 2, 3, or 86.

75. The method according to claim 74, wherein said mammal is a human.

76. The method according to claim 74, wherein said deficiency is Factor VIII deficiency.

77. The method according to claim 74, wherein said disease responds to the administration of urokinase.

78. The method according to claim 74, wherein said disease responds to the administration of thrombin.

79. The method according to claim 74, wherein said deficiency is a glucosidase deficiency.

80. The method according to claim 74, wherein said deficiency is a galactosidase deficiency.

81. The method according to claim 80, wherein said deficiency is a Fabry's Disease.

82. The method according to claim 74, wherein said deficiency is a sulfatase deficiency.

83. The method according to claim 74, wherein said deficiency is an Immunoglobulin deficiency.

84. The method according to claim 74, wherein said disease responds to the administration of an Immunoglobulin.

85. The method according to claim 74, wherein said disease responds to the administration of Factor VIII.

86. A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the residual solvent content of said biological material;

(ii) adding to said biological material at least one stabilizer mixture

(iii) reducing the temperature of said biological material; and

(iv) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the temperature and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i), (ii) and (iii) may be performed in any order.

87. The method according to claim 2, wherein said residual solvent content is less than about 10%.